

SMA

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	09/724,551	SCHENK ET AL.
	Examiner	Art Unit
	Christopher Nichols, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 3 September 2003.
2.  The allowed claim(s) is/are 47 and 69-74.
3.  The drawings filed on 03 September 2003 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

5.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a)  The translation of the foreign language provisional application has been received.
6.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8.  CORRECTED DRAWINGS must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No. \_\_\_\_\_.
  - (b)  including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.**

9.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1 <input type="checkbox"/> Notice of References Cited (PTO-892)	2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____.
5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____.	6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment
7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance
	9 <input type="checkbox"/> Other

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. The Response/Amendment filed 3 September 2003 has been received and entered in full. Claims 47, 69, and 70 have been amended. Claims 1-46, 48-68 have been cancelled. Claims 72-74 have been added.

### ***Withdrawn Objections And/Or Rejections***

2. All previous Rejections and Objections not made herein are withdrawn.

### ***Terminal Disclaimer***

3. The terminal disclaimer filed on 14 November 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 09/724552 has been reviewed and is accepted. The terminal disclaimer has been recorded.

## **EXAMINER'S AMENDMENT**

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the claims:

Claims 1-46 (Cancelled)

Claim 47 (Currently Amended) A pharmaceutical composition comprising an antibody having human IgG1 isotype that specifically binds to an epitope within residues 1-7 of A $\beta$  and a pharmaceutical carrier, wherein the isotype of said antibody is human IgG1.

Claims 48-68 (Cancelled)

Claim 69 (Currently Amended) A The pharmaceutical composition according claim 47, wherein said antibody comprising an antibody that specifically binds to an epitope within residues 1-4 of A $\beta$  and a pharmaceutical carrier.

Claim 70 (Currently Amended) A The pharmaceutical composition according claim 47, wherein said antibody comprising an antibody that specifically binds to an epitope within residues 1-3 of A $\beta$  and a pharmaceutical carrier.

Claim 71 (Previously Amended) The pharmaceutical composition of claim 47, wherein the antibody specifically binds to an epitope within residues 3-7 of A $\beta$ .

Claim 72 (Currently Amended) A pharmaceutical composition comprising a chimeric, or humanized or human antibody that specifically binds to an epitope within residues 1-7 of A $\beta$  and a pharmaceutical carrier.

Claim 73 (Previously Added) The pharmaceutical composition of claim 47, which is a sustained release composition.

Claim 74 (Previously Added) The pharmaceutical composition of claim 72, which is a sustained release composition.

5. Authorization for this examiner's amendment was given in a telephone interview with Rosemaire Celli (Reg. No. 42,397) on 14 November 2003.

In the Title:

**N-TERMINAL AMYLOID-BETA ANTIBODIES**

**REASONS FOR ALLOWANCE**

6. The following is an examiner's statement of reasons for allowance:
7. The references cited herein were found by the Examiner during the art searches while preparing the instant Application for allowance. None of the references teach or fairly suggest a human antibody that is specific for an epitope within residues 1-12 (and subsets within) of A $\beta$ .
8. Claims 69 and 70 were amended to be dependent from claim 47 to correct an error made without deceptive intent made by Applicant in the Amendment filed 3 September 2003.

9. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

*Summary*

10. Claims 47 and 69-74 are hereby allowed.

11. The Examiner acknowledges that acceptance of the above Examiner’s Amendment does not mitigate in any way, shape, or form, Applicant’s right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
December 1, 2003

*Gary d. Kunz*  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
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